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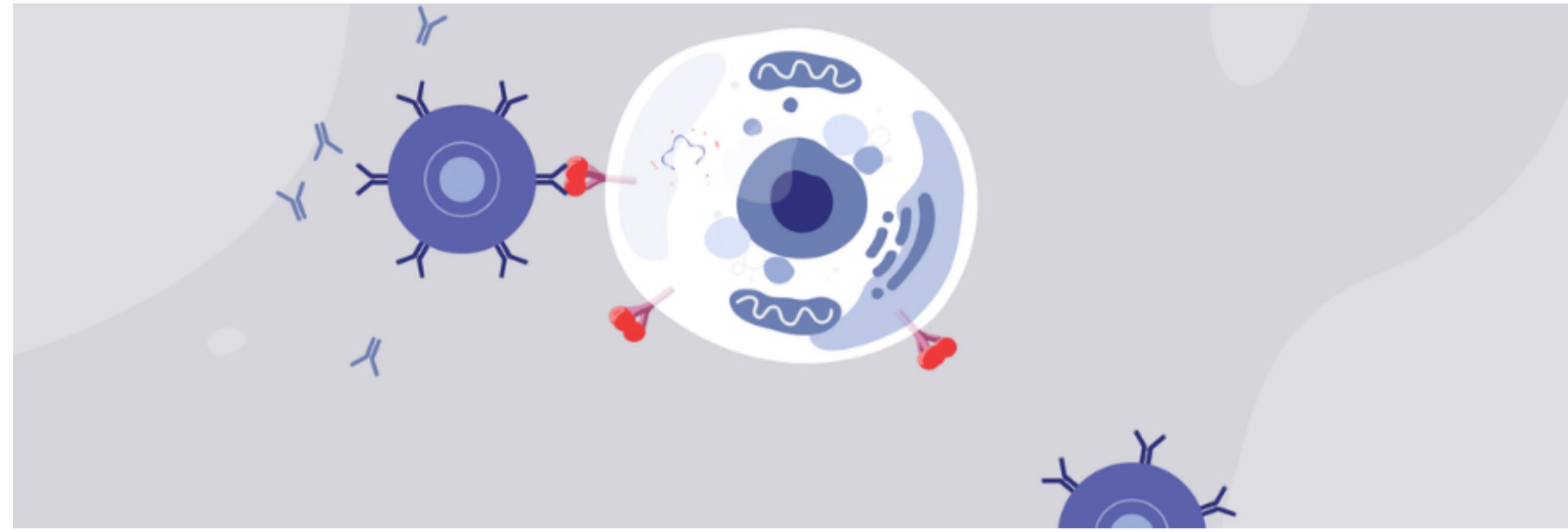
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Comirnaty Becomes First-Ever mRNA Vaccine to Receive FDA Approval

Beverly L. Davidson, PhD - August 27, 2021

ASGCT President Beverly L. Davidson, PhD, discusses this week's FDA approval of the Pfizer-BioNTech vaccine for COVID-19.



The FDA **approved the Pfizer-BioNTech COVID-19 vaccine** earlier this week, making it the first-ever mRNA vaccine or drug to receive approval from the Agency. The historic approval demonstrates that this mRNA vaccine is a safe and effective strategy to fight COVID-19.

The vaccine, which will now be marketed as Comirnaty, has been available under Emergency Use Authorization (EUA) since December. Acting FDA Commissioner Janet Woodcock, MD, said the approval **may now instill additional confidence for people to get vaccinated**. More than 92 million people in the U.S. have already received two doses of Comirnaty, **according to CDC data**.

Both Comirnaty and the Moderna vaccine **deliver synthetic mRNA** molecules into cells, instructing them to make antigens, or foreign invaders that the immune system recognizes as not being part of itself. In the case of the Comirnaty and Moderna vaccines, cells are instructed to make only the SARS CoV-2 spike protein, which is just enough to activate the immune system. Then, if a person is exposed to COVID-19, the immune system will detect the familiar antigens and produce antibodies to attack them. **Because the vaccine introduces new genetic material into cells for a short period of time to induce antibodies, it is a gene therapy as defined by ASGCT.** The mRNA in Comirnaty does not alter the recipient's genetic material and is only present in the body transiently. To learn more about how mRNA vaccines and other gene therapies work, you can visit **our Patient Education site**.

To support its approval decision, the FDA reviewed updated data from the clinical trial that supported the EUA and included a longer duration of follow up in a larger clinical trial population, ultimately determining the vaccine met the high standards for safety, effectiveness, and manufacturing quality the FDA requires. The FDA analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients who were 16 and older and did not have evidence of infection within a week of receiving the second dose. The Agency evaluated the safety of Comirnaty in approximately 22,000 people who were 16 and older and received the vaccine, and 22,000 people who received a placebo. Results from the clinical trial showed the vaccine was 91% effective in preventing COVID-19.

Comirnaty is still available under EUA for people between 12 and 15 years old and for the administration of a third dose in certain people who are immunocompromised.

I hope you'll join me in sharing this information with your family, friends, and others in your network to encourage more people to get vaccinated. Scientists, including many ASGCT members, have been researching the use of mRNA in medical interventions for decades, and we must take advantage of this incredible technology to build protection against COVID-19 in our communities.

Dr. Davidson is the president of ASGCT, director of the Raymond G. Perleman Center for Cellular and Molecular Therapeutics at the Children's Hospital of Philadelphia, and professor of pathology & laboratory medicine at the University of Pennsylvania.

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